REMARKS

Claims 1, 20, 22, 24, 26, 28, 31, 34, 37, 40, and 46 are pending in the instant application and have been subjected to a Restriction Requirement under 35 U.S.C. §121 as follows:

Group I, claims 1 and 20, drawn to a method of inducing differentiation of an isolated marrow stromal cell into an endodermal cell;

Group II, claim 22, 24, and 26, drawn to a method of treating a human patient having a disease comprising administering an endodermal cell, generated from isolated marrow stromal cell, into a subject;

Group III, claims 28 and 34, drawn to an isolated endodermal cell;

Group IV, claims 31 and 37, drawn to an isolated endodermal cell with a transgene;

Group V, claim 40, drawn to an isolated cell culture that expresses both an endodermal and ectodermal cell marker;

Group VI, claim 46, drawn to a method of producing an isolated neuronal precursor cell comprising isolating a marrow stromal cell and culturing the cell to produce a cell that expresses both an endodermal and ectodermal cell marker.

The Examiner acknowledges that the inventions of Group III and Group I are related as product and process of use; however it is suggested that because the product can be used *in vitro* and the method can be used practiced with cells from other sources, the inventions of Groups I and III are distinct. It is also suggested that Inventions of Groups III and IV as well as the inventions of Groups V and III are related as mutually exclusive species in an intermediate-final product relationship. The inventions of Groups

I, II, and VI are suggested as being unrelated because they are different methods that use different starting materials, use and require different method steps and result in different outcomes. The Examiner further acknowledges that the inventions of Group VI and Group V are related as process of making and product made; however it is suggested that because the product can be obtained from other sources and the method appears to be capable of making a variety of cell types, the inventions of Groups I and III are distinct. The Examiner acknowledges that were Applicants to elect claims directed to a product, and the product claim were subsequently allowed, withdrawn process claims that depend from or otherwise include all limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.04. Applicants are required to elect one of the Groups to be examined. Applicants respectfully disagree and traverse this restriction requirement.

MPEP §803 is quite clear; for a proper restriction requirement, it must be shown: (1) that the inventions are independent or distinct AND (2) that there would be a serious burden on the Examiner if the restriction is not required. MPEP 802.01 defines "distinct" to mean that the "two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made there, etc., but are capable of separate manufacture, use, or sale, as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER."

Applicants believe that restriction of the claims as set forth in this paper is not proper. In particular, it is respectfully pointed out that the method of Group I (claims 1 and 20) and the

method of Group VI (claim 40) employ the same starting material (*i.e.*, a marrow stromal cell) and result in the same outcome (*i.e.*, an endodermal cell). As such, the methods of Group I and VI overlap in scope and are therefore not distinct. Moreover, given that the claims of Groups I and VI have been classified in class 435, subclass 325, there would be no additional burden placed on the Examiner to search and exam together the overlapping methods of Group I and Group VI. MPEP §803 indicates that if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. Applicants submit that the claims are related and further that the search burden on the Examiner will not be increased due to inclusion of Groups I and VI in this application. Reconsideration and withdrawal of this Restriction Requirement is therefore respectfully requested.

Applicants also respectfully submit that the endodermal cells and cell cultures of Group III, Group IV, and Group V have been improperly restricted. MPEP 806.05(j) indicates that "an intermediate product and a final product can be shown to be distinct inventions if the intermediate and final products are mutually exclusive inventions (not overlapping in scope) that are not obvious variants, and the intermediate product as claimed is useful to make other than the final product as claimed. Typically, the intermediate loses its identity in the final product." Applicants submit that the endodermal cells of claims 31 and 37 (Group IV) as well as the individual cells of the culture of claim 40 (Group V) still retain their identity as endodermal cells. As specified in claims 31 and 37 (Group IV), the expression of the

therapeutic protein or peptide serves to effect the treatment of a disease, disorder, or condition associated with a tissue of endodermal origin; said expression does not alter the identity of the cell to another cell type. Likewise, claim 40 (Group V) specifies that the cell culture comprises cells that are characteristic of endodermal and ectodermal cell types. As such, the cells of the culture of claim 40 retain the identity of ectodermal cells. Therefore, the cells of Group III, Group IV, and Group V overlap in scope and are not mutually exclusive inventions under MPEP §806.05(j). Reconsideration and withdrawal of this Restriction Requirement is therefore respectfully requested.

However, in an earnest effort to be completely responsive, Applicants hereby elect to prosecute Group I, claims 1 and 20, drawn to a method of inducing differentiation of an isolated marrow stromal cell into an endodermal cell, classified in class 435, subclass 325, with traverse.

Respectfully submitted,

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